

6P 1642

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/280

APR 03 2002

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Applicant: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS FACTOR

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on <u>3/29/02</u>	<u>Stacy McGarry</u>
Date	Signature
<u>STACY MCGARRY</u>	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents

P.O. Box 2327

Arlington, VA 22202

Sir:

This Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's
Initials

- _____ U.S. Patent Application No. 09/766,535, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 18, 2001, Docket No.: 0975.1005-010
- _____ U.S. Patent Application No. 09/897,724, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 2, 2001, Docket No.: 0975.1005-012
- _____ U.S. Patent Application No. 10/010,229, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed December 7, 2001, Docket No.: 0975.1005-014
- _____ U.S. Patent Application No. 10/043,450, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-015

U.S. Patent Application No. 10/044,534, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-016

U.S. Patent Application No. 10/043,432, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-017

U.S. Patent Application No. 10/043,436, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-018

Examiner

Date

- [] A copy of each above-cited application, including the current claims, is enclosed.
- [X] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

March 29, 2002

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
0975.1005-013APPLICATION NO.
09/927,703INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

March 29, 2002

(Use several sheets if necessary)

APPLICANT
Junming Le, et al.FILING DATE
August 10, 2001GROUP
1642

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	FILED DATE IF APPROPRIA

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATI ON YES NO
AQ5	WO91/09967	11 JUL 91	PCT			
AL6	0486526B2	07 MAR 01	EPO			
AM6	WO92/02190	10 JUN 92	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AT7	Whittle, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," <i>J. Cell Biochem</i> , Supl. 13A:96 (1989).
AU7	Gorman, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," <i>Sem Immunol</i> , 2:457-466 (1990).
AV7	Starnes, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal <i>Escherichia Coli</i> Infection and Lethal Tumor Necrosis Factor Challenge in Mice," <i>J Immunol</i> , 145:4185-4191 (1990).

EXAMINER

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FOREIGN PATENT DOCUMENTS

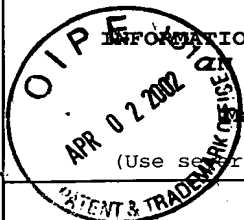
DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)


AW7	Duncombe, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," <i>J Immunol</i> , 143:3828-3834 (1989).
AX7	Aderka, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," <i>J Immunol</i> , 143:3517-3523 (1989).
AY7	Aderka, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," <i>Isr J Med Sci</i> , 27:52-60 (1991).
AZ7	Lassalle, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," <i>Int Arch Allergy Appl Immunol</i> , 94:233-238 (1991).
AR8	Fong, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," <i>Clin Immunol Immunopathol</i> , 55:157-170 (1990).
AS8	Eck, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor- α at 2.6 Å Resolution," <i>J Biol Chem</i> , 264:17595-17605 (1989).
AT8	Gillies, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," <i>J Immunol Methods</i> , 125:191-202 (1989).
AU8	Kameyama, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," <i>FEBS Lett</i> , 244:301-306 (1989).

EXAMINER

DATE CONSIDERED



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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703			
 INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 29, 2002 (Use several sheets if necessary)		APPLICANT Junming Le, et al.		RECEIVED APR 03 2002 TECH CENTER 1600/2009			
		FILING DATE August 10, 2001				GROUP 1642	
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AV8	Hayashi, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," <i>Recent Adv. Chemother</i> , 820-821 (1985).					
	AW8	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J Immunol Methods</i> , 96:57-62 (1987).					
	AX8	Sunahara, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor α and its antibodies using a bacterial cell wall carrier," <i>J Immunol Methods</i> , 109:203-214 (1988).					
EXAMINER			DATE CONSIDERED				